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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,815	07/09/2001	Lars Lannfelt	LANNFELT1A	9645

466 7590 11/09/2005

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/899,815

Applicant(s)

LANNFELT ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27,32,33,44,45 and 48-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27,32,33,44,45 and 48-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. After final amendment submitted on October 07, 2005 has been entered in full. Claims 27 and 52 have been amended and claims 24, 39-43 and 47 have been canceled as requested in the amendment filed on October 07, 2005. Following the amendment, claims 27, 32-33, 44-45 and 48-60 are pending in the instant application.

Claims 27, 32-33, 44-45 and 48-60 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Upon further consideration and in view of Applicant's newly presented amendments, finality of the last office action is withdrawn and prosecution on the merits of this application is reopened on claims 27, 32-33, 44-45 and 48-60.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 27, 32-33, 44-45 and 48-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treatment of Alzheimer's disease by administration of an antibody that specifically binds to A $\beta$ -Arc peptide, does not reasonably provide enablement for methods of prevention of Alzheimer's disease by administration of an antibody that specifically binds to A $\beta$ -Arc peptide. The specification does not enable any person

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skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 27, 44 and 51 are directed to methods of prevention and treatment of Alzheimer's disease by means of administration of a therapeutically effective amount of an antibody that specifically binds to A $\beta$ -Arc peptide. Claims 32-33, 45, 48-50 and 52-60 are dependent claims. The instant specification provides guidance on how to practice the claimed methods with respect to treatment of Alzheimer's disease only. The state of the art of Alzheimer's disease is such that etiology of the disease is currently unknown and no prophylactic treatment is available. There is no known causes that lead to accumulation of pathogenic amyloid fibrils on the brain of Alzheimer's disease patients (see Vickers, 2002, *Drugs Aging*, 19 (7), pp.487-494, for example). The instant specification fails to provide evidence or sound scientific reasoning that preventive administration of antibodies developed against A $\beta$ -Arc peptide to healthy individuals would lead to prevention of Alzheimer's disease. In view of the absence of this critical information, one skilled in the art would have to resort to substantial amount of undue experimentation in order to discover how to practice the full scope of the instant invention, as currently claimed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 27, 32-33, 44-45 and 48-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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8. Claims 27, 44 and 51 are vague and indefinite because it is not clear and cannot be determined from the claims or instant specification if an antibody that is raised against a protofibril comprising an A $\beta$ -Arc peptide has the ability to specifically bind to A $\beta$ -Arc peptide to the exclusion of other A $\beta$  peptide. If this is the case, Applicant is advised that adding recitation "wherein said antibody binds to said A $\beta$ -Arc peptide" would obviate this ground of rejection.
9. Claim 55 recites the limitation " A $\beta$ 41-Arc" in claim 27. There is insufficient antecedent basis for this limitation in the claim.
10. Claims 32, 33, 45, 48-50, 52-54 and 56-60 are indefinite for being dependent from indefinite claims.

#### ***Double Patenting***

11. Applicant is advised that should claim 45 be found allowable, claim 52 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the scope of claims 45 and 52 appears to be undistinguishable.

#### ***Specification***

12. Applicant is advised that in case of amendment to obviate the rejection under 35 U.S.C. 112, first paragraph, section 5 of the instant office action, an amendment to the title of the invention would be required to exclude "prevention" of Alzheimer's disease.


***Conclusion***

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

November 7, 2005